IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
COLUMBUS DIVISION

IN RE MENTOR CORP. OBTAPE	*	MDL Docket No. 2004 4:08-MD-2004 (CDL)
TRANSOBTURATOR SLING PRODUCTS	*	
LIABILITY LITIGATION	*	Case Nos. 4:08-cv-05000 (Crews *et al.*)

O R D E R

This multidistrict litigation proceeding includes various product liability actions against Mentor Worldwide LLC ("Mentor") arising from the implantation of Mentor's suburethral sling product, ObTape Transobturator Tape ("ObTape"), to treat Plaintiffs for stress urinary incontinence ("SUI"). The litigation has been divided into phases, and the present Order applies to the Phase I Plaintiffs ("Plaintiffs") who are Plaintiffs in the case of *Crews v. Mentor*, which was originally filed in the United States District Court for the Central District of California.[1] In this action, Plaintiffs assert claims for design defect, manufacturing defect, failure to warn, and failure to recall.

Presently pending before the Court is Mentor's Motion for Summary Judgment on All Phase I Non-Georgia Plaintiffs' Fraud-on-the-FDA Claims (ECF No. 212 in 4:08-md-2004). As discussed

[1]Counsel for the parties informed the Court that they had reached settlements in the cases that originated with the law firm of Blasingame, Burch, Garrard & Ashley, including two of the three cases involving non-Georgia Phase I Plaintiffs, *Cree, et al. v. Mentor*, 4:08-cv-5003, and *Doria, et al. v. Mentor,* 4:08-cv-5010. Accordingly, the Court dismissed those cases. Order of Dismissal, ECF No. 380 in 4:08-md-2004.

below, the Court finds that to the extent Plaintiffs alleged any fraud-on-the-FDA claims, such claims have been abandoned, and the summary judgment motion as to those claims is therefore granted.

Also pending before the Court are Mentor's summary judgment motions as to the non-Georgia Phase I Plaintiffs' claims for design defect, manufacturing defect, failure to warn, and failure to recall (ECF No. 192 in 4:08-cv-5000 (Suriani Plaintiffs); ECF No. 193 in 4:08-cv-5000 (Plaintiff Thompson); ECF No. 194 in 4:08-cv-5000 (Oliver Plaintiffs)). For the reasons set forth below, Mentor's summary judgment motions are denied as to those claims. Plaintiffs concede that their other claims—for intentional infliction of emotional distress, breach of express warranty, and negligent misrepresentation—fail as a matter of law. Pls.' Resp. to Mentor's Mots. for Summ. J. 47, ECF No. 222 in 4:08-cv-5000. Therefore, the Court grants Mentor's summary judgment motions as to those claims.

SUMMARY JUDGMENT STANDARD

Summary judgment may be granted only "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c)(2). In determining whether a *genuine* issue of *material* fact exists to defeat a motion for summary judgment, the evidence is viewed in the light most favorable to the party opposing summary

judgment, drawing all justifiable inferences in the opposing party's favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). A fact is *material* if it is relevant or necessary to the outcome of the suit. *Id.* at 248. A factual dispute is *genuine* if the evidence would allow a reasonable jury to return a verdict for the nonmoving party. *Id.*

FACTUAL BACKGROUND

The evidence relevant to the pending summary judgment motions can be divided into two categories: (1) evidence that relates to all Plaintiffs' claims, and (2) evidence that relates specifically to each Plaintiff. The Court will discuss each category of evidence separately, starting with the evidence that is relevant to all Plaintiffs' claims. The record, with all reasonable inferences construed in favor of Plaintiffs, establishes the following.

I. Evidence Relevant to All Plaintiffs' Claims

In support of their summary judgment motions related to all Plaintiffs' claims for design defect, manufacturing defect, failure to warn, and failure to recall, Mentor submitted evidence that overlaps substantially with the evidence Mentor submitted in support of its summary judgment motions as to the Phase I Georgia Plaintiffs' claims. In response, Plaintiffs rely on their Statement of Material Facts in Response to Defendant's Motions for Summary Judgment as to the Phase I Georgia Plaintiffs, as well as the supporting exhibits.

Pls.' Consol. Resp. in Opp'n to Mentor's Mots. for Summ. J. 4 n.1, ECF No. 222 in 4:08-cv-5000; *see* Pls.' Separate Statement of Material Facts in Supp. of Resp. in Opp'n to Def.'s Mots. for Summ. J., ECF No. 180 in 4:08-md-2004. All of that evidence is explained in detail in the Court's summary judgment order as to the Phase I Georgia Plaintiffs. *In re Mentor Corp. Obtape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1354-57, 1369-75 (M.D. Ga. 2010) [hereinafter *In re Mentor*]. The Court incorporates by reference its previous discussion of the facts relevant to all Plaintiffs.

II. Evidence Regarding Individual Plaintiffs

A. Erin Oliver

It is undisputed that, in 2005, Plaintiff Erin Oliver ("Ms. Oliver") consulted with Dr. Allen Ott regarding her SUI symptoms. It is also undisputed that, after discussing various treatment options with Dr. Ott, Ms. Oliver decided to go forward with suburethral sling surgery. Dr. Ott performed the surgery on Ms. Oliver, and he implanted ObTape. Following the surgery, Ms. Oliver experienced a number of complications, including an abscess that required hospitalization. She had several procedures to remove the ObTape and to treat the abscess. Rogers Decl. Unrestricted Ex. B, Oliver Dep. 131:10-134:23, June 18, 2009, ECF No. 222-6 in 4:08-cv-5000; Lewis Decl. Ex. H, Oliver Dep. 135:15-137:14, June 18 2009, ECF No. 194-6 in 4:08-cv-5000.

It is undisputed that Dr. Ott does not recall whether he read the ObTape product insert data sheet ("PIDS"). Dr. Ott's colleague did discuss ObTape with a Mentor representative, and the colleague relayed to Dr. Ott that ObTape was "fine," according to the Mentor representative. Lewis Decl. Ex. I, Ott Dep. 87:18-89:3, Sept. 15, 2009, ECF No. 194-6 in 4:08-cv-5000. Prior to Ms. Oliver's ObTape implant surgery, Dr. Ott attended a Mentor training session regarding ObTape and received certain materials regarding ObTape. *Id.* at 90:3-18. Dr. Ott stated that no one from Mentor ever told him that ObTape had a higher risk of erosion and infection than other tapes. Rogers Decl. Unrestricted Ex. G, Ott Decl. ¶¶ 6, 8-12, ECF No. 222-7 in 4:08-cv-5000. Dr. Ott further stated that he would not have used ObTape if he had known of the increased risks. *Id.* ¶¶ 7, 13.

B. Amber Suriani

It is undisputed that Plaintiff Amber Suriani ("Ms. Suriani") consulted with her OB/GYN regarding her SUI symptoms in December 2004; Ms. Suriani's OB/GYN referred her to Dr. Joel Bass to discuss the possibility of suburethral sling surgery. It is also undisputed that, after discussing various treatment options with Dr. Bass, Ms. Suriani decided to go forward with suburethral sling surgery. Dr. Bass performed the surgery on Ms. Suriani, and he implanted ObTape. Following the surgery, Ms. Suriani experienced a number of complications, including infection, erosion of the ObTape, and a

relapse of her SUI symptoms. She had six excision procedures to remove the eroded ObTape. Rogers Decl. Unrestricted Ex. A, Suriani Dep. 174:3-175:15; 183:4-6; 191:19-21; 201:3-24; 209:6-24; 214:2-215:3, July 10, 2009, ECF No. 222-5 in 4:08-cv-5000.

It is undisputed that Dr. Bass does not recall whether he read the ObTape PIDS. Prior to Ms. Suriani's ObTape implant surgery, Dr. Bass did speak with a Mentor representative regarding ObTape, and he attended a training seminar during which he saw a PowerPoint presentation containing favorable information about ObTape. Rogers Decl. Unrestricted Ex. F, Bass Decl. ¶ 4, ECF No. 222-7 in 4:08-cv-5000. Dr. Bass stated that no one from Mentor ever told him that ObTape had a higher risk of erosion and infection than other tapes. *Id.* ¶¶ 7-11. Dr. Bass further stated that he would not have used ObTape if he had known of the increased risks. *Id.* ¶¶ 12-13.

C. Deirdre Thompson

It is undisputed that Plaintiff Deirdre Thompson ("Ms. Thompson") consulted her physician, Kenneth Mitchell, regarding her SUI symptoms. It is also undisputed that, after discussing various treatment options with Dr. Mitchell, Ms. Thompson decided to go forward with suburethral sling surgery. Dr. Mitchell performed the surgery on Ms. Thompson, and he implanted ObTape. Following the surgery, Ms. Thompson experienced a number of complications, including infection, erosion of the ObTape, and abscesses that

required prolonged hospitalization. She had several excision procedures to remove the eroded ObTape. Rogers Decl. Unrestricted Ex. D, Thompson Dep. 149:6-150:8, 152:7-9, May 6, 2009, ECF No. 222-6 in 4:08-cv-5000.

It is undisputed that Dr. Mitchell read the ObTape PIDS prior to Ms. Thompson's ObTape implant surgery. Dr. Mitchell stated that he did not expect ObTape to have more severe and unusual complications than another suburethral sling product with which he was familiar. Ex. 36 to Mentor's Mot. to Exclude Certain Test. from Pls.' Proposed Expert Witnesses, Mitchell Rule 26 Report 1-2, ECF No. 156-6 in 4:08-md-2004, at 57-58. After Thompson's ObTape implant surgery, Dr. Mitchell became aware that several of his ObTape patients had severe and unusual complications. *Id.* at 2. For that reason, Dr. Mitchell stopped using ObTape to treat his patients. *Id.*

DISCUSSION

I. Fraud-on-the-FDA Claims

Mentor contends that Plaintiffs assert fraud-on-the-FDA claims in this action and that such claims are preempted by federal law. *See generally Mem.* in Supp. of Def.'s Mot. for Summ. J. on All Phase I Non-Georgia Pls.' Fraud-on-the-FDA Claims, ECF No. 212-2 in 4:08-md-2004. Plaintiffs represent that they are not asserting fraud-on-the-FDA claims. Pls.' Resp. in Opp'n to Def.'s Mot. for Summ. J. on All Phase I Non-Georgia Pls.' Fraud-on-the-FDA Claims 2, ECF No. 227

in 4:08-md-2004. The Court thus deems any such claims to be abandoned. *See In re Mentor*, 711 F. Supp. 2d at 1353 n.2 (finding fraud-on-the-FDA claims to be abandoned by Phase I Georgia Plaintiffs).

Plaintiffs maintain, however, that they should be permitted to introduce evidence regarding Mentor's alleged misstatements to the FDA "to provide the trier-of-fact with a background of [Mentor's] conduct concerning [ObTape]." Pls.' Resp. in Opp'n to Def.'s Mot. for Summ. J. on All Phase I Non-Georgia Pls.' Fraud-on-the-FDA Claims 3. This issue would best be handled via motions in limine before the Court that will try this action. *See In re Mentor*, 2010 WL 1734638, at *2 (M.D. Ga. Apr. 23, 2010). The Court notes that the Phase I Georgia Plaintiffs made a similar argument, and the Court concluded that evidence related to the FDA regulatory process—including evidence that the FDA cleared ObTape for sale and never took enforcement action against Mentor regarding ObTape and evidence regarding fraud on the FDA—was irrelevant to the claims and issues at issue in the Phase I Georgia Plaintiffs' actions. Pretrial Conference Tr. 174:9-175:16, May 3, 2010, ECF No. 299 in 4:08-md-2004.

II. Design Defect Claims

Plaintiffs contend that ObTape was defectively designed. As under Georgia law, a product is defective under California law if it

"has an inherent risk of danger that outweighs its benefits." *Hufft v. Horowitz*, 5 Cal. Rptr. 2d 377, 379 (Cal. Ct. App. 1992); *see In re Mentor*, 711 F. Supp. 2d at 1364-65 (discussing elements of design defect claim under Georgia law). Under California law, the "risk/benefit test considers factors such as seriousness of the potential danger, likelihood of its occurrence, and feasibility, cost and "adverse consequences to the product and the consumer of a safer alternative design." *Hufft*, 5 Cal. Rptr. 2d at 379-80 (internal quotation marks omitted). These factors are similar to the factors considered under Georgia law. *See In re Mentor*, 711 F. Supp. 2d at 1364 (discussing Georgia's risk-utility factors).

The Court previously found that genuine issues of material fact exist as to whether ObTape's risks outweighed its benefits. *Id.* at 1368-76. The evidence related to Plaintiffs' design defect claims in this action is the same as the evidence that was before the Court when ruling on Mentor's summary judgment motions as to the Phase I Georgia Plaintiffs' design defect claims. Therefore, for the reasons set forth in the Court's summary judgment order regarding the Phase I Georgia Plaintiffs' design defect claims, the Court concludes that summary judgment is not warranted on Plaintiffs' design defect claims.

III. Manufacturing Defect Claims

Plaintiffs also contend that the ObTape they received contained manufacturing defects. To prevail on their manufacturing defect claims, Plaintiffs must show that they were injured due to "a flaw in the manufacturing process, resulting in a product that differs from the manufacturer's intended result." *Brown v. Superior Court*, 751 P.2d 470, 474 (Cal. 1988). Under California law, a manufacturing defect exists if the product was not manufactured in conformity with the manufacturer's design. *In re Coordinated Latex Glove Litig.*, 121 Cal. Rptr. 2d 301, 315 (Cal. Ct. App. 2002). This standard is the same as the standard under Georgia law. *See In re Mentor*, 2010 WL 711 F. Supp. 2d at 1365 (discussing elements of manufacturing defect claim under Georgia law).

The Court previously found that genuine issues of material fact exist as to whether ObTape was manufactured in conformity with Mentor's design specifications. *Id.* at 1376-77. The evidence related to Plaintiffs' manufacturing defect claims in this action is the same as the evidence that was before the Court when ruling on Mentor's summary judgment motions as to the Phase I Georgia Plaintiffs' manufacturing defect claims. Therefore, for the reasons set forth in the Court's summary judgment order regarding the Phase I Georgia Plaintiffs' manufacturing defect claims, the Court concludes

that summary judgment is not warranted on Plaintiffs' manufacturing defect claims.

IV. Failure-to-Warn Claims

Plaintiffs further allege that Mentor failed to provide adequate warnings regarding the risks associated with ObTape and that Plaintiffs were injured as a result of the inadequate warnings. Under California law, a product manufacturer may be held liable under a failure-to-warn theory if the manufacturer "did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution." *Carlin v. Superior Court*, 920 P.2d 1347, 1351 (Cal. 1996). California, like Georgia, employs a learned intermediary doctrine under which a medical device manufacturer has a duty to warn the *physician* regarding the risks of a medical device and has no duty to warn the patient. *Id.* at 1354 (explaining California learned intermediary doctrine); *In re Mentor*, 711 F. Supp. 2d at 1365-66 (explaining Georgia learned intermediary doctrine). Thus, if a medical device manufacturer gives an adequate warning regarding potential dangers of the device to doctors who prescribe it, there is no duty for the manufacturer to warn the patients directly. *Carlin*, 920 P.2d at 1354 (citing *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973).

The Court previously found that genuine issues of material fact exist as to whether Mentor provided an adequate warning regarding ObTape under Georgia law. *In re Mentor*, 711 F. Supp. 2d at 1377-78. The evidence related to Plaintiffs' failure-to-warn claims in this action is the same as the evidence that was before the Court when ruling on Mentor's summary judgment motions as to the Phase I Georgia Plaintiffs' failure-to-warn claims. As discussed in the Court's summary judgment order regarding the Phase I Georgia Plaintiffs' failure-to-warn claims, genuine issues of material fact exist as to whether Mentor's ObTape warning was adequate because there is a fact question as to whether ObTape had a greater propensity to cause erosions and infections than other suburethral sling products whose warnings were nearly identical to the ObTape warnings. *Id.* The same evidence creates a genuine issue of material fact under California law, which requires that a manufacturer warn of risks that are "known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution." *Carlin*, 920 P.2d at 1351. Therefore, even though Mentor generally warned about the risks of erosion and infection associated with ObTape, the Court cannot conclude that the warnings were adequate as a matter of law given the evidence of ObTape's increased risks that were not addressed in Mentor's warnings. Furthermore, each of Plaintiffs' doctors stated that they were not

aware of the increased risks of ObTape and that they would not have used ObTape had they known of the increased risks. Accordingly, and for the reasons set forth in the Court's summary judgment order regarding the Phase I Georgia Plaintiffs' failure-to-warn claims, the Court concludes that Mentor is not entitled to summary judgment on Plaintiffs' failure-to-warn claims.

V. Failure to Recall

Finally, Plaintiffs claim that Mentor should be held liable under a failure to recall theory. California law does recognize that a manufacturer may be held liable if it negligently fails to act after the product has been distributed to its end user. For example, a product manufacturer may be held liable for failing "to conduct an adequate retrofit campaign." *Hernandez v. Badger Constr. Equip. Co.*, 34 Cal. Rptr. 2d 732, 754 (Cal. Ct. App. 1994); *cf. Valentine v. Baxter Healthcare Corp.*, 81 Cal. Rptr. 2d 252, 265 (Cal. Ct. App. 1999) (noting that product manufacturer has "an *ongoing* duty to warn of side effects 'known or knowable' in the scientific community"). Thus, the Court concludes that California law recognizes a failure to recall cause of action.

Mentor argues that California does not recognize such a cause of action in a medical device case *unless* the U.S. Food and Drug Administration ("FDA") has ordered the product off the market. The Court notes that Mentor's continued pursuit of this argument would

likely open the door to Plaintiffs' evidence regarding the alleged fraud on the FDA, which the Court found would otherwise be irrelevant. In any event, citing *Ramirez v. Plough, Inc.*, 863 P.2d 167 (Cal. 1993), Mentor contends that Plaintiffs cannot assert a failure to recall claim in this action. In *Ramirez*, the plaintiff, a child, alleged that he contracted a "rare and poorly understood illness" as a result of taking children's aspirin, and he sought to hold the manufacturer liable for failing to withdraw the product. *Ramirez*, 864 P.2d at 178. The *Ramirez* court emphasized that few scientific studies existed regarding the connection between aspirin and the disease, that the FDA looked at the issue and decided that further studies were needed, and that the FDA concluded that product warnings were an adequate public safety measure. *Id.* The *Ramirez* court also noted that the FDA's conclusion was "not binding" but that the plaintiff had not submitted any evidence to cause the court to doubt the FDA's decision that aspirin could be considered a reasonably safe product for children when distributed with appropriate warnings. *Id.* Thus, the FDA's decision not to take enforcement action is not dispositive where the manufacturer does not disclose all of a product's risks to the FDA. Plaintiffs have pointed the Court to evidence from which a factfinder could conclude that Mentor did not disclose certain information to the FDA that should have been disclosed under FDA regulations. *E.g.*, Ex. 40 to

Mentor's Mot. to Exclude Certain Test. from Pls.' Proposed Expert Witnesses, Samaras Rule 26 Report 2-5, 10-11, 37-39, ECF No. 156-7 in 4:08-md-2004, at 31-34, 39-40, 66-68. Accordingly, *Ramirez* does not mandate summary judgment as to Plaintiffs' failure to recall claim, and Mentor's summary judgment motion as to that claim is denied.

CONCLUSION

For the reasons set forth above, Mentor's Motion for Summary Judgment on All Phase I Non-Georgia Plaintiffs' Fraud-on-the-FDA Claims (ECF No. 212 in 4:08-MD-2004) is granted. Mentor's summary judgment motions are denied as to Plaintiffs' claims for design defect, manufacturing defect, failure to warn, and failure to recall (ECF No. 192 in 4:08-cv-5000 (Suriani Plaintiffs); ECF No. 193 in 4:08-cv-5000 (Plaintiff Thompson); ECF No. 194 in 4:08-cv-5000 (Oliver Plaintiffs)). Mentor's summary judgment motions are granted as to Plaintiffs' claims for intentional infliction of emotional distress, breach of express warranty, and negligent misrepresentation.

IT IS SO ORDERED, this 29th day of October, 2010.

S/Clay D. Land
CLAY D. LAND
UNITED STATES DISTRICT JUDGE